



# PROMECON

## Student / Master Thesis (Regulatory Affairs)

### Development and Implementation of an International Regulatory Strategy for a Prefilled Syringe System

#### We are

PROMECON is a family-owned company based in Hamburg, which manufactures and distributes single use medical devices. With more than 10 years of experience, we are a leading provider of elastomeric infusion pumps on the German market.

#### Outline

Prefilled syringes are a combination of a medical device and a medicinal product. Whereas the mode of action of medical devices is mainly physical, the medicinal products mode of action can be immunologic, metabolic, or pharmacologic. For such combination products not only medical device jurisdiction needs to be considered but also the jurisdiction for medicinal products/drugs.

The approach of this student thesis is the development and implementation of a regulatory strategy for a prefilled syringe for the US, UK, and EU markets.

The results of this thesis shall support the approval of the prefilled syringe in the forementioned markets.

#### Tasks

- Analyse the applicable jurisdictions (regulations, directives, national law, guidance, standards) and build a regulatory framework for prefilled syringes for the US, UK, and EU markets
- Build the relevant documentation
  - Communication with stakeholders
  - Create documents on your own
  - Evaluate what is needed to fulfil the general safety and performance requirements
- Develop a regulatory strategy for market approval in the US, UK, and EU
- Evaluate what would be needed for different scenarios (Promecon as legal manufacturer, Promecon as distributor etc.)

#### Your Profile

- Biomedical engineering student or similar field of education
- Basic experience in Regulatory Affairs
- Basic experience in Regulation (EU) 2017/745 and Directive 2001/83/EC of advantage
- Work in autonomous and target orientated manner

#### We offer

- Interdisciplinary, open minded and dynamic team
- Family-owned business with short decision-making processes
- Individual support of the thesis

#### Contact

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